

REMARKS

Claims 17 – 36 are pending.

Claims 1 and 37 – 54 are withdrawn from consideration.

PRIORITY

Applicants' claim of priority of U. S. Serial Nos. 08/533,942, 09/031,572 and 09/426,325 stands denied. The Examiner alleges that the application adds and claims additional disclosure not presented in the prior applications. Specifically, the alleged additional disclosure is a kit which comprises a nucleic acid comprising a gene encoding p21 and a catheter.

Applicants' incorporation-by-reference of U.S. Patent No. 5,328,470 into the present application is proper

Applicants respectfully traverse the Examiner's denial of priority. In rejecting Applicants' priority claim, the Examiner cites *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973) ("Seversky") in support of his position that the mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. §112, first paragraph.

Seversky addresses the issue of whether a statement in an application stating that the application is a "continuation-in-part" of a prior application is sufficient to incorporate therein any part of the prior application and rules that the "continuation-in-part" statement is insufficient to incorporate any part of the prior application. *Id.* at 146. In Seversky, the citing application contained no

“incorporation-by-language”, its only relation to the prior application being a statement that it was a “continuation-in-part” of the earlier application. Seversky states that a reference is properly incorporated “by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found”. *Id.*

The instant application does not make a “mere reference” to the ‘470 patent. Instead, the specification properly incorporates the ‘470 patent by the incorporation-by-reference statement on page 10 at lines 20-24.

The ‘470 patent teaches a method for the direct treatment towards specific sites of a disease (see Abstract). The method is based on the delivery of proteins by catheterization to discrete blood vessel segments, including the use of vector systems. Kits including a catheter and an expression vector are described at multiple places in the ‘470 specification, including at column 14, lines 61-66, column 15, lines 5-9, and in claim 9.

The Applicants submit that that holding in Seversky does not provide a basis for the Examiner’s assertion that Applicants’ incorporation-by-reference of the ‘470 patent fails to satisfy the disclosure requirements of 35 U.S.C. §112, first paragraph.

Applicants also respectfully traverse the Examiner’s assertion that Applicants’ incorporation-by-reference statement is defective because the relevant columns and line numbers of the ‘470 patent are not recited in the instant specification. While MPEP §608.01(p) states that the referenced

document should be identified in the referencing application, the MPEP does not require that page and line numbers be specified.

Accordingly, Applicants incorporation-by-reference statement is proper and the specification of the instant application supports the claims directed to a kit comprising a catheter and a nucleic acid comprising a gene encoding p21.

Applicants also properly incorporated the '470 patent by-reference into the '942, '572, and '325 applications

For the reasons stated above, the Applicants respectfully traverse the Examiner's assertion that the '942, '572, and '325 parent applications do not incorporate the '470 patent by reference. All three references contain a proper incorporation-by-reference statement. For example, U.S. Patent Number 5,563,904, which issued from the '942 application, contains such a statement in column 5 at lines 8-10. The specification states that the "composition[s] of the present invention are preferably administered by direct injection of the expression vector (or a liposome containing the same) into the tumor such as described in U.S. 5,328,470, incorporated herein by reference".

Since, the priority documents also contain proper incorporation-by-reference statements, these applications also support claims directed to a kit comprising a catheter and a nucleic acid comprising a gene encoding p21. Withdrawal of the Examiner's denial of priority is respectfully requested for the reasons stated above.

OATH/ DECLARATION

The Examiner states that the application presents a claim for subject matter not originally claimed or embraced in the statement of the invention and requires a new oath/ declaration. Applicants submit that as a result of the incorporation by reference of the '470 patent, and for the reasons stated above with respect to priority, no new matter is presented. For this reason, withdrawal of the Examiner's request for a new oath/ declaration is respectfully requested.

35 U.S.C. §112, FIRST PARAGRAPH REJECTIONS

Claims 17 – 36 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, claim 17, and dependent claims 18 – 36, are directed to a kit comprising a catheter and a nucleic acid comprising a gene encoding p21. The Examiner admits that the Applicants' disclosure provides support for the use of a catheter and an expression vector comprising a gene encoding p21 in a treatment method (Paper No. 12, page 7 – Office Action mailed 9/12/2002) but alleges that the specification provides no implicit or explicit support for a kit comprising a catheter and a nucleic acid comprising a gene encoding p21.

The Examiner also alleges that the specification provides no implicit or explicit support for claim 18, directed to a kit comprising a catheter and a nucleic

acid comprising a gene encoding p21, wherein the catheter is a single-balloon catheter.

Applicants respectfully traverse the Examiner's rejection. As discussed above with respect to Applicants' priority claim, the specification discloses a combination of a catheter and a nucleic acid encoding p21. By the proper incorporation by reference of the '470 patent on page 10 at lines 20-24, the specification teaches that such combinations may be included in a kit. Applicants submit that they have met the requirements of 35 U.S.C. §112, first paragraph, regarding written description. Withdrawal of the Examiner's 35 U.S.C. §112, first paragraph rejection is requested for the reasons stated above.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 17 and 19 – 36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Nabel *et al.* (U.S. Patent No. 5,863,904) ("the '904 patent"). Applicants respectfully traverse the Examiner's rejection. In view of the arguments made above with respect to the priority of the instant application, Applicants submit that this application is entitled to a priority date of September 26th, 1995. Accordingly, the '904 patent, which issued on Jan 26, 1999 cannot anticipate the present claims because it was not published more than one year prior to the priority date of the present application.

In addition, Applicants submit that to the extent that the Examiner applies the '904 patent to reject claims 17 and 19 – 36 under 35 U.S.C. §102(b), this supports Applicants' contention that the '904 patent supports claims directed to a

kit comprising a catheter and a nucleic acid encoding p21. In rejecting Applicants' priority claim the Examiner states that such a kit is not presented in the '904 patent (08/533,942) (Paper No. 12, page 2). But if the '904 patent anticipates the pending claims, these elements must necessarily be present. Applicants therefore request that the Examiner withdraw the 35 U.S.C. §102(b) rejection of claims 17 and 19-36.

Favorable consideration and allowance of this application are respectively requested for the reasons set forth in the above remarks. If, for any reason, the Examiner is unable to allow the application on the next Office Action and feels that an interview would be helpful to resolve any remaining issues, he is respectfully requested to contact the undersigned attorney at (312) 321-4229.

Respectfully submitted,

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John Murray

John Murray, Ph.D.
Registration No. 44,251
Attorney for Applicants

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
Telephone: (312) 321-4200